COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17/03/2003
C(2003) 851

NOT FOR PUBLICATION

COMMISSION DECISION

of 17/03/2003

amending Decision C(2000)1407 on the marketing authorization for the medicinal product for human use

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC.

COMMISSION DECISION

of 17/03/2003

amending Decision C(2000)1407 on the marketing authorization for the medicinal product for human use

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "PegIntron - Peginterferon alfa-2b" entered in the Community register of medicinal products under Nos EU/1/00/131/001-050 authorised by Commission Decision C(2000)1407 of 25 May 2000, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Schering Plough Europe submitted an application on 26 July 2002 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 18 December 2002 by the Committee for Proprietary Medicinal Products,

(4) Decision C(2000)1407 should therefore be amended accordingly.

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;

2. Annex III B is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 17/03/2003

For the Commission
Erkki LIIKANEN
Member of the Commission